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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,525	06/04/2001	Stephen M. Allen	BB-1316	5276

7590 07/14/2004

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EXAMINER

BUI, PHUONG T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,525

Applicant(s)

ALLEN ET AL.

Examiner

Phuong T. Bui

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Claims 25-36 are pending and are examined in the instant application.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See pages 8 and 18, for example.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "a polypeptide having SNF4 activity". Neither the state of the art nor Applicant's disclosure defines what SNF4 activity encompasses. The specification states "The SNF4 gene encodes a 32 kDa protein kinase whose activity is functionally related to SNF1 and evidence suggest that SNF4 physically interacts with the SNF1 protein as a positive effector" (p. 1). However, it is unclear how the two kinase activities are related, how they are different, and how one skilled in the art would be able to determine from a population of polypeptides which would have "SNF4 activity" as encompassed by the claims. While "SNF4" may be an art-recognized term, "SNF4 activity" is not defined. Accordingly, one would not be

Art Unit: 1638

reasonably apprised of the metes and bounds of the claimed invention based upon said recitation.

Claim Rejections - 35 USC 101 Utility

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 25-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. The claimed invention does not meet the utility requirements under current utility guidelines for the following reasons. First of all, Applicant does not disclose that SEQ ID NO:1 encodes a complete protein; and SEQ ID NO:1 does not appear to contain a complete open reading frame since it does not begin with the start codon methionine. In Applicant's response to the restriction requirement filed May 19, 2004, Applicant indicates "The first methionine of SEQ ID NO:2 is at amino acid number 7". While this is correct, this does not address whether the methionine at a.a. position 7 is the start codon methionine or a subsequent methionine of an incomplete SNF4 protein. Applicant's description of the claimed sequence as submitted to A_Geneseq database indicates SEQ ID NO:2 is a partial sequence (Allen et al., Acc. No. AAY96783, A_Geneseq database, 22 June 2000 (V)). Further, neither Applicant's disclosure nor the state of the prior art at the time the invention was made provides guidance as to where the catalytic domain(s) of Applicant's SNF4 is located. No empirical data are presented to verify that SEQ ID NO:1 or a nucleotide sequence encoding SEQ ID NO:2 encodes a protein having SNF4 activity. While empirical data are not required, sequence

Art Unit: 1638

alignment is generally useful in placing a protein in a particular class but does not replace verification of function. Moreover, while the complete protein is substantially useful in controlling carbon and nitrogen partitioning pathways in plants (specification, p. 2), an incomplete protein without enzymatic activity would not have substantial utility. Table 4 (p. 20) shows that SEQ ID NO:2 has 51% sequence identity with an SNF4 sequence obtained from *Arabidopsis thaliana*. However, it is unclear whether the prior art sequence used for sequence alignment with Applicant's SEQ ID NO:2 is a complete protein, and what the sequence identity would be if both the prior art sequence and Applicant's sequence are complete SNF4 proteins. Since SEQ ID NO:1 encodes a partial protein and does not appear to contain the catalytic domain(s) necessary for enzymatic function, the utility for such a sequence would be lacking. It would also follow that sequences having less than 100% sequence identity to SEQ ID NO:2 would also lack utility for the same reasons.

Secondly, the claimed invention lacks substantial utility because Applicant does not teach how the claimed invention can be used to achieve a real-world use. Applicant states that plant genes involved in catabolite regulation of various metabolic pathways may be used in plants to control carbon and nitrogen partitioning pathways during plant growth and development (pages 1 and 2), but Applicant does not teach how the claimed polynucleotide encoding a polypeptide having SNF4 activity should be used to affect carbon and nitrogen partitioning in a useful manner? Furthermore, what does carbon and nitrogen partitioning ultimately lead to—more vegetative growth, disease resistance, increase of lipids or proteins in plant storage organs? It is apparent that

Art Unit: 1638

further research is required before the claimed polynucleotide would be of benefit to the public. However, the courts have decided that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use lacks substantial utility.

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (Brenner v. Manson, 383 U.S. 519 (1966)).

Thus, while regulating certain genes for certain traits would provide substantial benefit to the public, the claimed invention is not refined and developed to the point where specific benefit exists, as no guidance is provided as to how SEQ ID NO:1 should be used to alter any specified plant trait. Accordingly, the claimed invention lacks specific asserted utility.

Additionally, there is no well-established utility for SEQ ID NO:1 and a sequence encoding SEQ ID NO:2. SEQ ID NO:1 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed sequences lack utility (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claim Rejections - 35 USC § 112, first paragraph

7. Claims 25-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Additionally, claims

Art Unit: 1638

reciting less than 100% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining SNF4 activity, however such activity is defined. Applicant provided no working examples or further guidance as to which region(s) of SEQ ID NO:1 are conserved domains necessary for protein activity. While skilled in the art can readily make base changes, further guidance is necessary as to what changes would be tolerated without undue experimentation. Accordingly, the claimed invention is not enabled.

8. Claims 25-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having less than 100% sequence identity to SEQ ID NO:2. However, the translated amino acid sequence SEQ ID NO:2 appears to be only a partial sequence of a protein (see utility rejection above). SEQ ID NO:1, which encodes SEQ ID NO:2, is only a partial gene sequence and does not contain a complete open reading frame encoding a complete protein. However, the "comprising" language in the claims reads upon complete gene sequences having in common a nucleotide sequence encoding SEQ ID NO:2. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the complete structure of a gene encoding an SNF4 protein based upon the disclosure of a partial sequence, absent

Art Unit: 1638

further guidance. Accordingly, one skilled in the art would not recognize from Applicant's disclosure of SEQ ID NO:1 that Applicant is in possession of the complete gene encoding a complete SNF4 protein.

The claims reciting less than 100% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass SNF4 proteins from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:1 isolated from *Zea mays*. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants and allelic variants of other *Zea mays* plants, or the structure of SNF4 proteins from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Remarks

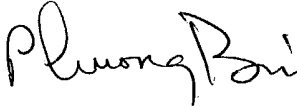
9. No claim is allowed. SEQ ID NO:1 and a nucleotide sequence encoding SEQ ID NO:2 are free of the prior art. The closest prior art teaches a sequence isolated from *Arabidopsis thaliana* having 51% sequence identity with SEQ ID NO:2 (Table 4, p. 20; and Osborne et al., Accession No. O04028, SPTEEMBL_25, 01 July 1997 (U)).

Art Unit: 1638

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Phuong T. Bui
Primary Examiner
Art Unit 1638

7/12/04

07/12/04